



MICHIGAN  
**BRAIN & SPINE**  
INSTITUTE

November 30, 1999

7010 '99 DEC -7 10:21

Document Management Branch (HFA-305)  
Food and Drug Administration  
5630 Fishers Lane, Room 1061  
Rockville, MD 20852

To Whom This Letter Presents:

This is a letter in reference to **Docket No. 97N-484S**. It is a physician comment regarding the efficacy and safety of the use of allograft bone dowels as medical implant devices.

We have had a little over one year experience utilizing allograft bone dowels as medical devices in approximately 72 cases. To date there has been no failure of the device *in vivo*. Specifically, we have not seen any fatigue fracturing or disintegration of the bone dowel device to date. There has been good maintenance of the intravertebral body disc space height with very little subsidence. It is too early to comment on fusion rates, though they are at least comparable to, if not better than, metal implant cylindrical devices.

There are several *in vivo* clinical trials currently ongoing comparing bone dowel implants to metal implant devices. We are presently involved in such a trial and have noted no significant difference between the two. We think it would be practical and prudent for the FDA to review and utilize these current clinical trials to determine safety issues rather than subjecting bone banks to premarket trial requirements, the sponsoring of clinical trials, and submitting lengthy regulatory documentation for a product that's already in the *in vivo* stages of utilization.

We are happy to meet and/or discuss with anyone the efficacy of utilizing bone dowels and/or metal devices for interbody fusion techniques.

Sincerely,

Geoffrey M. Thomas, M.D., F.A.C.S.

GMT/leo (d: 113099 t: 113099)

cc: E. Ron Pickard  
President  
Medtronic Sofamor Danek  
1800 Pyramid Place  
Memphis, TN 38132

**Neurological  
and Spine Surgery**

S. M. Farhat, MD, FACS  
Steven E. Swanson MD, FACS  
Geoffrey M. Thomas, MD, FACS  
Jason A. Brodkey, MD  
Martin J. Buckingham, MD, FACS  
E.A. Kahn, MD, 1900-1985

**Spine and  
Orthopaedic Surgery**

Mark A. Falahee, MD, FACS  
Douglas E Geiger, MD

**Pediatric Spine Surgery**

Douglas E. Geiger, MD

Reichert Health Building  
Suite R-3112.  
PO Box 994  
Ann Arbor, MI 48106  
734 434-4110  
734 434-1966 FAX  
1-800-824-9253

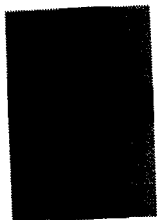
Michigan Orthopaedic Center  
5315 Elliott Drive  
Suite 102  
Ypsilanti, MI 48197  
734 4344 110  
734 572-9455 FAX  
1-800-824-9253

With offices in Chelsea  
and Brighton

A Professional  
Corporation

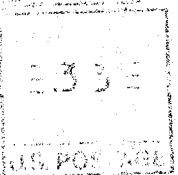
97N-484S

C 33



MICHIGAN  
**BRAIN & SPINE**  
INSTITUTE

Michigan Orthopaedic Center  
5315 Elliott Drive, Suite 102  
Ypsilanti, MI 48197



20537-0001

